

## REMARKS

### **I. Status of the Application**

Claim 26 is pending in the application. Claim 26 stands rejected under 35 U.S.C. § 112, second paragraph. Claim 26 also stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Benoit et al., U.S. Patent No. 6,087,003.

Applicants have amended the claim under consideration to more clearly define and distinctly characterize Applicants' novel invention. Applicants have added new claims 27-46. Support for the amendments to claim 26 can be found in the specification at least at page 11, lines 15-18 where the vessel is described as having an aperture to avoid increasing the internal pressure and to allow the natural release of carbon dioxide gas out of the calcifying solution. Support for newly added claims 27, 29-38, and 40-43 can be found in the specification, at least at page 10, line 8 to page 11, line 31. Support for newly added claims 28, 39 and 44 can be found in the specification at least at page 19, lines 6-30, and in Figure 1. Support for newly added claims 45 and 46 can be found in the specification, at least at page 10, line 8 to page 11, line 31, and page 19, lines 6-30, lines 6-30, and in Figure 1. The amendments and newly added claims contain no new matter.

Attached hereto is a marked-up version of the changes made to the claims captioned "Version of Amendments With Markings To Show Changes Made."

### **II. Claim 26 is Definite**

At page 3, paragraph 2 of the present Office Action, claim 26 stands rejected under 35 U.S.C. § 112, second paragraph. The Examiner states that claim 26 is confusing because it is unclear how the implant support relates to other elements of the apparatus. Applicants have

amended the claim to recite that implant support is operatively connected to the reactor vessel, support for which is found at least at page 11, lines 1-3 of the specification. Therefore, Applicants respectfully submit that the amended claim is allowable, and request that the Examiner reconsider and withdraw this rejection.

### **III. Claim 26 is Nonobvious Over Benoit et al.**

At page 2, paragraph 3 of the instant Office Action, claim 26 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Benoit et al., U.S. Patent No. 6,087,003. The Examiner asserts that Benoit et al. teaches the design of a coating apparatus having a reaction vessel, heating element, stirrer, inlets, outlets, and a controlled source of carbon dioxide operatively connected to an inlet. The Examiner is of the opinion that absent a clear recitation of how the implant support relates to the reactor vessel, it would have been obvious to modify the Benoit et al. apparatus by providing a support for the implant since it is conventional to do so in a coating apparatus. The Examiner is further of the opinion that it would have been obvious to coat a variety of materials to be used as an implant since it is known to implant pharmaceutical compositions. The Examiner admits that Benoit et al. fails to teach an implant support and end use of a coating apparatus for coating an implant.

Applicants respectfully traverse the Examiner's rejection based on the amended claims now presented. Applicants respectfully submit that to establish a *prima facie* case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.

Applicants' amended claims are directed to a device for coating an implant comprising a reactor vessel, a heating element, an implant support, a stirrer, an inlet connected to a controlled

source of carbon dioxide, and an outlet configured to avoid increasing internal pressure of the reactor vessel.

Benoit fails to teach or suggest a reactor vessel having an outlet configured to avoid increasing internal pressure of the reactor vessel. Quite the opposite, the device of Benoit et al. uses high pressures to coat substrates. Benoit et al. teaches the use of a pressurized system for coating substrates whereby the substance is suspended in a supercritical fluid and placed into an autoclave or an apparatus which comprises a pressurizable reaction chamber (column 3, lines 10-30). Benoit et al. teaches that typical operating conditions for coating a substrate include pressures of 70-250 bars, although higher pressure may be used (column 5, lines 51-56). Benoit et al. further teaches that “[o]nce deposition of the desired coating material is complete, the system is depressurized” (column 10, lines 62-65). Furthermore, each of the twenty-five working examples of Benoit et al. teach the use of very high pressures when coating substances, ranging from 110 bar to 200 bar.

In contrast, Applicants' device includes an outlet configured to avoid increasing internal pressure of the reactor vessel. As a result, during operation of the reactor vessel the system is non-pressurized and allows the exchange of dissolved gas with the atmosphere. Thus, Applicants' device has structure not taught by Benoit et al. and that allows it to operate in a completely different manner than the pressurized apparatus of Benoit et al.

In addition, applicants respectfully submit that Benoit teaches away from applicants' invention. One of skill in the art when reviewing the disclosure of Benoit et al. directed to a pressurized system and the 25 examples using high pressures to accomplish coating, would not be motivated to modify Benoit et al. to operate without pressure, as to do so would not suggest that a working embodiment based on Benoit et al would result.

**IV. Conclusion**

Having addressed all outstanding issues, Applicants respectfully request reconsideration and allowance of claim 26 and consideration and allowance of claims 27-46. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

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**VERSION OF AMENDMENTS WITH MARKINGS TO SHOW CHANGES MADE**

26. (Amended) A device for coating an implant comprising:

- (a) a reactor vessel;
- (b) a heating element operatively connected to the reactor vessel;
- (c) an implant support operatively connected to the reactor vessel;
- (d) a stirrer disposed within the reactor vessel;
- (f) an inlet and outlet operatively connected to the reactor vessel; [and]
- (g) a controlled source of carbon dioxide operatively connected to the inlet, and,

wherein the outlet is configured to avoid increasing internal pressure of the reactor vessel.

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